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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,686	07/31/2001	Stephen Alister Locarnini	37921-151956	7052

23973 7590 11/10/2005

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EXAMINER

PENG, BO

ART UNIT PAPER NUMBER

1648

DATE MAILED: 11/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/831,686	<b>Applicant(s)</b> LOCARNINI ET AL.	
	<b>Examiner</b> Bo Peng	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13,15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-13,15 and 17 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

1. Applicant's preliminary amendment filed July 13, 2004 is acknowledged.

Claims 14 and 16 are cancelled

Claims 13 and 15 have been amended.

Claims 1-13, 15 and 17 are pending.

2. It is noted that claim 17 is directed to the "use" of a variant HBV or an HBsAg.

Applicant is advised that "use" claims are non-statutory. For the purposes of restriction, claim 17 is read as a composition comprising an isolated HBV or an HBsAg. Correction is required.

### ***Election/Restrictions***

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4 and 13, drawn to the specific technical feature of a variant HBV comprising an amino acid sequence of formula I and a composition comprising a variant HBV.

Group II, claim(s) 1, in part, 5 and 13, drawn to the specific technical feature of a variant comprising a nucleotide sequence of formula III and a composition.

Group III, claim(s) 6, 7 and 13, drawn to the specific technical feature of an isolated variant HBsAg or a recombinant for or a derivative comprising altered amino acid sequence and immunological profile and a composition comprising a HBsAg.

Group IV, claim(s) 7, in part, 8 and 13, drawn to the specific technical feature of a variant HBV encoded by a nucleotide sequence and a composition.

Group V, claim(s) 9 and 13, drawn to the specific technical feature of a variant HBV or an isolated HBsAg having mutations on the catalytic region of HBV DNA polymerase and a composition.

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Group VI, claim(s) 10 and 13, drawn to the specific technical feature of a variant HBV or variant HBsAg having specific mutations and a composition.

Group VII, claim(s) 11 and 13, drawn to the specific technical feature of a variant HBV or variant HBsAg having specific mutations and a composition.

Group VIII, claim(s) 12 and 13, drawn to the specific technical feature of a variant HBV or variant HBsAg having specific mutations and a composition.

Group IX, claim(s) 15, drawn to the specific technical feature of a method for the treatment or prophylaxis of HBV infection.

4. If Group I, II, III, IV, V, VI, VII OR VIII above is elected, Applicant is required to elect ONE isolated HBV or HBsAg by a specific SEQ ID NO for examination.

5. The technical feature of group I appears to be isolated HBV variant. However, 5,591,440 teaches mutant HBV and its diagnostic and therapeutic application.

The inventions listed as Groups I-IX are not related to a single general inventive concept under PCT Rule 13.1 because, under PCT rule 13.2, they lack the same or corresponding special technical features. As set forth above, each group requires a special technical feature that is not required by any of the other groups. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Bo Peng, Ph.D.  
November 1, 2005



**JEFFREY STUCKER**  
**PRIMARY EXAMINER**